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Evaluation of Two Mechanical Ventilators for Use in U.S. Army Combat Support Hospitals

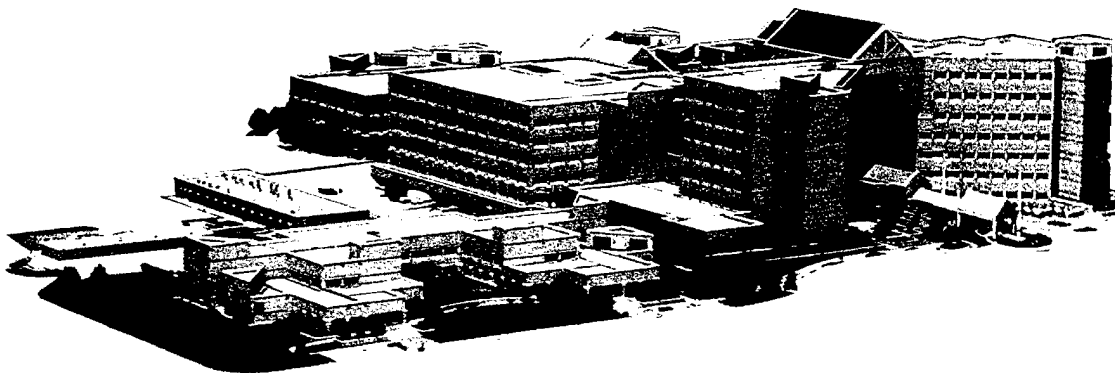
SGT William VanPutte

SFC Tia Arevalo

SFC Dominique Greydanus

LTC Leopoldo Cancio

June, 2004



UNITED STATES ARMY INSTITUTE OF SURGICAL RESEARCH FORT SAM HOUSTON TEXAS

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13. ABSTRACT (Maximum 200 words) Patients who cannot or will not be evacuated to a fixed facility for an extended period of time may require long-term ventilator care. We studied two ventilators to determine which could better fulfill the needs of Army Combat Support Hospitals. VersaMed iVent and Drager Savina ventilators were tested in a 22-day study at the U.S. Army Institute of Surgical Research, Fort Sam Houston, Tx; Brooke Army Medical Center, Fort Sam Houston, TX; and Camp Bullis, TX between 14 April and 5 May 2004. Battery life and charge time, durability of ventilators underfield conditions, physical properties and restrictions, and ease of use were examined. Battery charge time for the iVent was nearly 4 times longer than for the Savina ventilator in our test. The iVent outperformed the Savina ventilator in the other categories. Both ventilators present limitations such as yearly checkup requirements by company-certified technicians, obligatory battery recharge every 6 months, and storage temperature restrictions. The life of the internal batteries for both devices was short (approximately one hour). Of the two ventilators, our testing and user feedback recommend the VersaMed iVent ventilator. For either ventilator the purchase of optional external batteries should be considered.				
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DEPARTMENT OF THE ARMY
U.S. ARMY INSTITUTE OF SURGICAL RESEARCH
3400 RAWLEY E. CHAMBERS AVENUE, BLDG 3611
FORT SAM HOUSTON, TEXAS 78234-6315

REPLY TO
ATTENTION OF

MRMC-USM (70-1y)

22 Jun 2004

MEMORANDUM FOR COMMANDER

SUBJECT: Information Copy of Manuscript

1. The manuscript titled "Evaluation of Two Mechanical Ventilators for Use in U.S. Army Combat Support Hospitals" by SGT William VanPutte et al. has been reviewed by this Command and meets acceptable standards for publication. The manuscript contains no matter that warrants disapproval for security or policy reasons.
2. The above manuscript has been submitted to the Defense Technical Information Center (DTIC) to be released as a technical report.

A handwritten signature in cursive script, reading "Leopoldo C. Cancio", is positioned above the printed name.

LEOPOLDO C. CANCIO
LTC(P), MC
Acting Commander

Enclosure

CF:
Cdr, MRMC, ATTN: RMI-S
SGT VanPutte



DEPARTMENT OF THE ARMY
U.S. ARMY INSTITUTE OF SURGICAL RESEARCH
3400 RAWLEY E. CHAMBERS AVENUE, BLDG 3611
FORT SAM HOUSTON, TEXAS 78234-6315

REPLY TO
ATTENTION OF

MEMORANDUM FOR DIRECTOR OF RESEARCH

7 June 2004

SUBJECT: Manuscript Review

1. I have reviewed the attached manuscript and appropriate committee approval (IACUC/IRB) titled "Evaluation of VersaMed iVent and Drager Savina Ventilators" by SGT William D. VanPutte. This work represents the results of experiments conducted under:

Title of Protocol: N/A

Protocol Number: N/A

Principal Investigator: N/A

2. The manuscript meets the requirements of good scientific merit.

3. I recommend that the attached manuscript be approved for submission to DTIC as a technical report

LEE CANCIO
LTC(P), MC
Chief, Burn Center

RECOMMENDATION:

APPROVAL / DISAPPROVAL

ROBERT M. WILDZUNAS
MAJ, MS
Director of Research

Evaluation of Two Mechanical Ventilators
For Use in U.S. Army Combat Support Hospitals

SGT William D. VanPutte, U.S. Army

SFC Tia Arevalo, U.S. Army

SFC Dominique Greydanus, U.S. Army

LTC Leopoldo C. Cancio, MC, U.S. Army

U.S. Army Institute of Surgical Research, Fort Sam Houston, TX 78234

The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or as reflecting the views of the Department of the Army or the Department of Defense. The mention of specific products does not constitute an endorsement.

ABSTRACT

Objective: Patients who cannot or will not be evacuated to a fixed facility for an extended period of time may require long-term ventilator care. We studied two ventilators to determine which could better fulfill the needs of Army Combat Support Hospitals.

Methods: VersaMed iVent and Drager Savina ventilators were tested in a 22-day study at the U.S. Army Institute of Surgical Research, Fort Sam Houston, TX; Brooke Army Medical Center, Fort Sam Houston, TX; and Camp Bullis, TX between 14 April and 5 May 2004. Battery life and charge time, durability of ventilators under field conditions, physical properties and restrictions, and ease of use were examined. Testing was conducted in five phases:

Phase 1: Test battery life

Phase 2: Test battery charge time

Phase 3: Test ventilator performance under field conditions

Phase 4: Test ventilator compliance

Phase 5: Test ease of use

Results: Battery charge time for the iVent ventilator was nearly 4 times longer than for the Savina ventilator in our test. The iVent outperformed the Savina ventilator in the other categories. Both ventilators present limitations such as yearly checkup requirements by company-certified technicians, obligatory battery recharge every 6 months, and storage temperature restrictions. The life of the internal batteries for both devices was short (approximately one hour).

Conclusion: Of the two ventilators, our testing and user feedback recommend the VersaMed iVent ventilator. For either ventilator the purchase of optional external batteries should be considered.

TESTING

Phase 1. Battery Life

Both ventilators come equipped with internal batteries. Testing of ventilator life running on internal battery power was conducted at two different levels. For the first test ventilators were run at normal adult settings for tidal volume (VT), respiratory rate (RR), positive end expiratory pressure (PEEP), pressure support (PS), and peak flow (PF): VT 700, RR12, PEEP5, PS10, and PF60. Ventilators were run until they stopped operating. For the second test ventilators were run at higher VT and faster RR: VT 900, RR16, PEEP5, PS10, and PF70. Ventilators were run until they stopped operating.

Test 1

Ventilators were charged for a day, then run fully charged, unplugged from the external electrical supply, and monitored for alarms and power. The table below lists the major alarms (see Appendix A for complete list of alarms).

	1 st Alarm	1 st Message	2 nd Alarm	2 nd Message	Battery Stopped
Drager Savina	+ 51 min.	"Int Batt Almost Discharged"	None	None	+ 57 minutes
VersaMed iVent	+ 56 min.	"Battery Empty"	+ 77 min	"VT not delivered"	+ 85 minutes

Test 2

Ventilators were charged overnight, then run fully charged, unplugged from the external electrical supply, and monitored for alarms and power. The table below lists the major alarms (see Appendix A for full list of alarms).

	1st Alarm	1st Message	2nd Alarm	2nd Message	Battery Stopped
Drager Savina	+ 43 min.	“Int Batt Almost Discharged”	None	None	+ 47 minutes
VersaMed iVent	+ 61 min.	“Battery Empty”	+ 74 min	“VT not delivered”	+ 85 minutes

Comment: External batteries can be purchased for either ventilator. Manufacturers state that external batteries have longer lives than internal batteries. Because external batteries are not part of standard ventilator packages they were not evaluated.

The VersaMed iVent safe operating time was five minutes longer for Test 1 and eighteen minutes longer for Test 2 than the Drager Savina. We concluded that the safe operating time for either ventilator is the period before the 1st message is sent. This definition of the safe operating time would guarantee that the ventilators were working properly. Also, because the batteries would not be fully discharged at 1st message, charge times would be shorter. We do not recommend using the Drager Savina after the “Int Batt Almost Discharged” is displayed or after the VersaMed iVent displays the “Battery Empty” message due to the possibility of the ventilators stopping or not complying with settings.

Phase 2. Charge Time

Ventilators were run until internal batteries were completely discharged. Ventilators were then plugged in, put on stand-by, and monitored for charge time.

	Charge Time
Drager Savina	+ 132 min.
VersaMed iVent	+ 507 min.

Comment: The Drager Savina charge time was six hours and fifteen minutes faster than the VersaMed iVent. The Drager Savina does not display power level while plugged in, so we had to unplug the ventilator to check the battery life throughout the charging time. At 2 hours 12

minutes the Drager Savina indicated it was fully charged.

The VersaMed iVent always displays the current battery life. When the Savina was fully charged the VersaMed iVent was still reading a charge below 30%. We called the manufacturer who indicated that the battery could take eight to twenty-four hours to fully recharge after a complete discharge. We asked the night shift to check the ventilator and tell us when it indicated fully charged. The next day we were told that it took eight hours and twenty-seven minutes before the iVent was fully charged.

Due to the limited test time we were not able to check the charge time of a partially discharged battery, but the manufacturer stated that it would be faster.

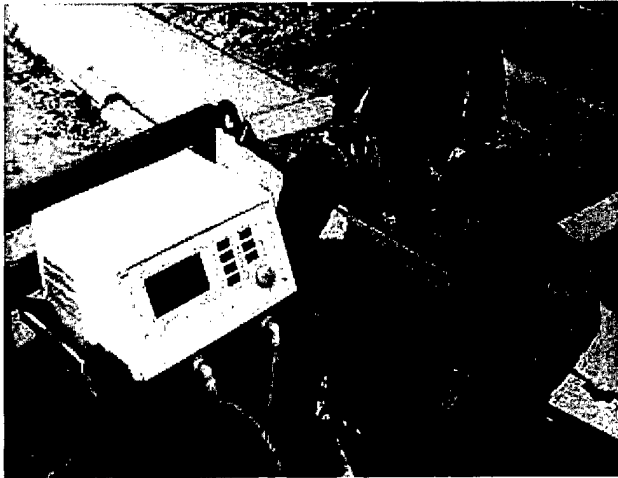
Phase 3. Field Test

Ventilator performance was checked during exposure to vibrations and dust in the back of a moving vehicle at Camp Bullis, Texas. We were given a M998 HUMMWV and a driver from "E" Company BAMC. The ventilators were placed on the crew seats and secured with patient litter straps.

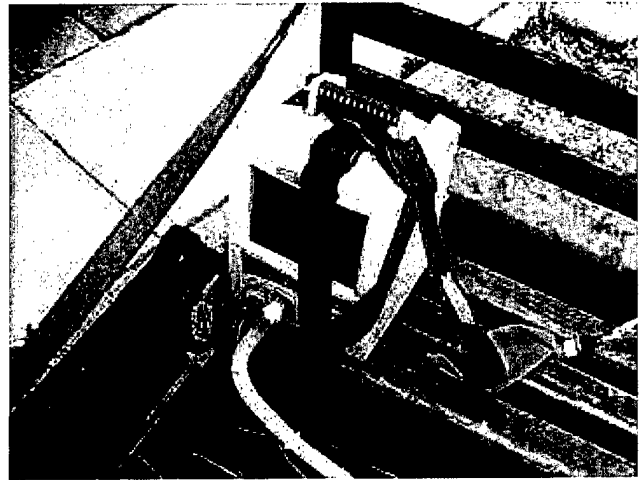
Vibration Testing

Vibration testing was conducted by driving on paved roads, dirt roads, and off road until the batteries were exhausted. Ventilator settings were VT 700, RR12, PEEP5, PS10, and PF70.

	Paved Road	Dirt Road	Off Road
Drager Savina	No problems	Minor problems	Minor problems
VersaMed iVent	No problems	No problems	Minor problems



Drager Savina secured to M998 HUMMWV



VersaMed iVent secured to M998 HUMMWV

Comment: The Drager Savina read some large bumps on the dirt road as inspiratory efforts and compensated by delivering additional breaths of around 100 ml. We changed the trigger from 2 L/min to 4 L/min which corrected the problem. Again, during the off road test the Drager Savina interpreted large bumps as inspiratory efforts and delivered additional breaths of around 100 ml. We were not able to increase the Drager Savina to 6 L/min because the ventilator ran out of power. Afterward we called the Drager representative (Denise Howmen) and were told that this problem has happened before and that we just needed to monitor the patient and adjust the sensitivity trigger. This could be a problem if the ventilators are used to evacuate large numbers of patients with minimal staff.

Off road the VersaMed iVent sensed large bumps as inspiratory efforts. We increased the flow/pressure trigger to -4 cmH₂O/4L which corrected the problem.

Both ventilators will have to be closely monitored if they are used to transport patients to insure that false breaths are not being delivered. Although triggers can be manipulated to compensate, the patient may have to work harder to get a spontaneous breath.

Dust

We tested for dust by driving on loosely packed dirt roads while operating the ventilators.

Comment: Due to rain the previous day there was not a lot of dust. Both units were coated with a film of dust at the conclusion of the test and operated with no problem from the dust that they were exposed to. If used in a dusty environment they are both going to need to have the filters cleaned out daily.

The ventilators should be tested in a hot dusty environment (possibly National Training Center (NTC)) to see how heat and dust affect both ventilator and battery operations.

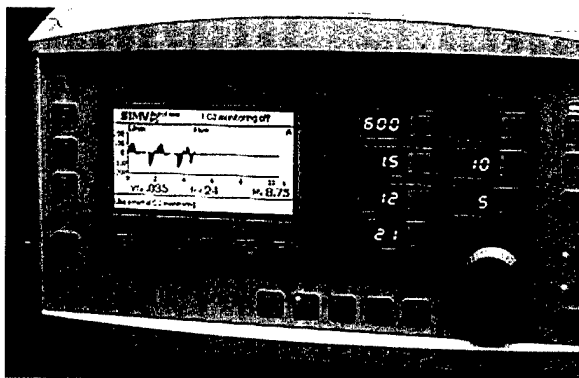
During road tests the transport bag that comes with the VersaMed iVent was not used because we wanted to see how the ventilator would operate if the bag was lost. The button on the front of the VersaMed iVent was hit several times by the litter straps that secured it resulting in the controls being activated, although this did not cause any problems at the time, if not caught it could result in unintentional changes in the settings. The transport bag comes with handles that should be used to secure the ventilator.

Phase 4. Compliance

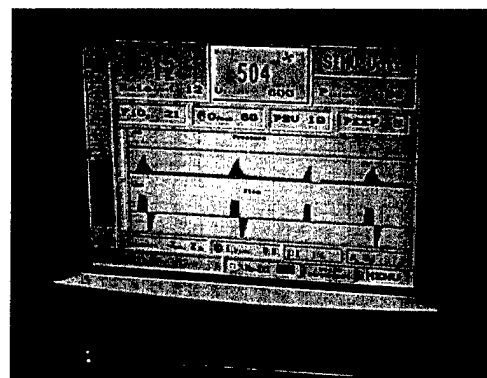
Ventilators were checked for exhaled VT while attached to a Michigan Instruments Training / Test Lung Model 2601. The test lung was set to 0.08 L/cmH₂O (normal), increased to 0.14 L/cmH₂O, and then decreased to 0.02 L/cmH₂O, while measuring the exhaled VT with a Medishield Wright Respirometer at least twice to insure the results were reproducible. Ventilator settings were VT 600, RR12, PEEP5, PS10, and PF60.

	Drager Savina		VersaMed iVent	
Compliance	Ventilator (ml)	Wrights (ml)	Ventilator(ml)	Wrights (ml)
0.14 L/cmH ₂ O	632 (+32 ml)	650 (+50 ml)	612 (+12 ml)	590 (-10)
0.08 L/cmH ₂ O	559 (-41 ml)	600 (=setting)	580 (-20 ml)	610 (+ 10 ml)
0.02 L/cmH ₂ O	560 (-40 ml)	780† (+180 ml)	504 (-96 ml)	600 (=setting)

† ventilator was auto-cycling and delivering an extra breaths after each mandatory breath with a set breath rate of 12 but a total breath rate was as high as 24 breaths per minute.



Drager Savina during decreased compliance test



VersaMed iVent during decreased compliance test

Comment: We called Drager about the Wright respirometer measurement of +180 ml and they stated that "...the Wright is not calibrated to certain flows and/or the change in flow may have affected the veins inside ... the Wright in the middle of the expiratory side was picking up the added volume that was being overcome in an effort to deliver the volume necessary..."

We put a new circuit on the ventilator and reset the device, without connecting a Wright respirometer and ran the ventilator again. The ventilator functioned in the same manner as the previous test. We connected a Wright respirometer to the exhalation side of the ventilator after

the exhalation value and measured the exhaled VT, and the readings were the same. We tried a different brand of respirometer and had the same results.

The VersaMed iVent functioned without any major problems during the compliance test, but the Drager Savina did not function well during the decreased compliance test (delivering 180ml more than what was set on the ventilator). Because of these discrepancies, if either ventilator is selected, I recommend that exhaled VT be measured daily with a Wright respirometer to insure whenever there is a change in compliance that the set VT is actually being delivered.

Phase 5. Ease of Use

Twenty-two respiratory therapists (RT) were selected to fill out an evaluation form and perform tests on the ventilators (see Appendix B for evaluation form and scores). One therapist acted as an evaluator while the other acted as controller and timed the evaluator. Of the twenty-two therapists, two were excluded because the test was not done correctly, and two were excluded because they did not fill out the form completely, resulting in only eighteen evaluation forms being used.

Comment: On average, therapists were able to enter the first settings into the VersaMed iVent in half the time it took to make entries into Drager Savina. Second settings were entered in about the same time for both ventilators. Most therapists thought that the VersaMed iVent was easier to operate and preferred it.

FURTHER EVALUATIONS

1. Comparison of Drager and VersaMed Specifications

	Drager Savina	VersaMed iVent201
Ventilation Modes ¹	CMV A/C SIMV CPAP/PS PCV (optional) Bi-Pap	A/C- volume & pressure SIMV - volume & pressure Adaptive Bi-level CPAP PSV
Respiratory Rate	2-80 bpm	1-50 bpm
Tidal Volume	0.05-2.0 L	1.0 -2.0 L
PEEP	0-35 cmH2O	0-20 cmH2O
PSV	0-35 cmH2O	0-60 cmH2O
Peak Flow	AutoFlow™ (optional) 1-180L/min	Adaptive Flow 1-120 L/min (180 spont)
Inspiratory Pressure	0-100 cmH2O	5-80 cmH2O
Inspiratory Time	0.2-10s	Adaptive Time 0.3-3s
O2 Concentration	21-100 %	21-100%
Low Flow O2	Yes	Yes
Dimensions W x H x D	15 x 15.1 x 14.1	9.5 x 13 x 10.3
Weight	49 lbs	22 lbs
Ventilator Circuit ²	Standard Circuit	Manufacturers' Circuit
Internal Battery Life Manufacturers' Specs	Approx 60 Min	Up to 2 hours
Optional External Battery	Yes, in stand	Yes, in carry case
External Battery Life	Approx 7 hours	Up to 4 hours
NBC Adapter ³	No	Yes
Output for pneumatic medication nebulizer ⁴	Yes	No

¹Both ventilators come with the standard modes of operation, and volume/pressure control. Auto Flow for the Drager Savina is optional; Adaptive Flow for VersaMed iVent is standard, which means that both the ventilators can sense a patients' peak flow needs and will adjust to those needs. The VersaMed iVent Bi-level non-invasive ventilation is standard, but is optional with the Drager Savina.

²The VersaMed iVent can use either a disposable or non-disposable ventilator circuit that can only operate on the iVent. Cost is about twice (around \$8.00 each) as much as a standard circuit like the kind used on a PB7200. A non-disposable circuit is available for \$250.00 each. The Drager Savina uses a standard disposable ventilator circuit like the kind used on a PB7200.

³The Versa Med iVent comes with an adapter that fits an NBC canister on the air inlet port.

⁴The Drager Savina comes with an output for a pneumatic medication nebulizer.

Battery Storage Data

	Drager Savina	VersaMed iVent201
Batteries	Should not be stored for extended periods over 50°C	-15 to 70° C / -4 to 140° F
	Needs to be charged every six months while in storage	Recharge every 90 days of storage
	Need to remove fuse for internal battery	

2. Maintenance

Although there is not much difference between the two ventilators when considering maintenance requirements, there are several maintenance issues to consider with each ventilator (see Appendix C for a complete list).

The Drager Savina requires an initial safety check after two years and yearly thereafter. The VersaMed iVent requires that parts to be checked yearly. The manufacturers for both ventilators require that maintenance tasks be performed by authorized technical personnel either on site or after shipping ventilators to manufacturer. Both ventilator companies, for a fee, offer classes to train local personnel to perform yearly checks.

Both ventilator manufacturers note storage temperature limitations. The Drager Savina cannot be stored at temperatures above 122°F / 50°C; the VersaMed iVent cannot be stored above 158°F / 70°C. Because most equipment is stored in Connexes (Container Extended) during deployment, heat will be a critical issue. The temperature inside a Connex could well exceed 122°F / 50°C in the Middle East which could result in damage to the Drager Savina.

Both ventilators batteries need to be charged after several months in storage. If the batteries can be removed from the ventilators and be charged at all times this would cut down on the possible damage to the batteries and the ventilators would be available for use at all times. At

this time neither manufacturer has a system for doing this, but VersaMed has stated that if needed they could make an external charger for their internal batteries.

3. User Feedback

The VersaMed iVent is currently being used by the Israeli Defense Force (IDF). The Head of Trauma Branch of the IDF Medical Corps (LTC Amir Blumenfeld) stated, "All physicians (anesthesiologists and surgeons) that used it were very satisfied with the machine and no significant pitfall or complaint was raised. In addition, we used it during air transfer drills where we applied intensive care capabilities. Again, trainees were satisfied and willing to use it instead of the old vents. The only time we actually used it, was during the transport of an injured female patient from Mombassa, Kenya to Tel-Aviv. She was injured in a terrorist attack, operated in Kenya and transported while being ventilated with the iVent. This transfer took about 10 hours flight with a C-130. The ICU physicians that used the vent during the flight were very happy with it. Their only remark was about the battery life which is relatively short. No problems were reported after connecting the vent to the aircraft electricity. . . .Another issue worth mentioning is the fact that this vent is 'user friendly.' It takes a very short time to train experienced personnel (anesthesiologists) and make them feel comfortable with the vent. As you understand I have no information about long term ventilation."

SUMMARY

Test comparisons concluded with the following results:

	Drager Savina		VersaMed iVent201	
Weight	49 lbs	-	22 lbs	+
Screen Size	Smaller	-	Larger	+
Total Ventilator Size	Larger	-	Smaller	+
Battery Life			Longer	+
Battery Message Display			Constant	+
Compliance	Poor	-	Good	+
Storage Temperature Tolerance	Lower	-	Higher	+
NATO NBC Filter Adapter	No		Yes	+
Off Road	Misinterpretation	-	Misinterpretation	-
Total Battery Charge Time	Faster x 3	+	Slower	-
Battery Maintenance	Every 6 months	+	Every 3 months	-
Ventilator Circuit	Standard	+	Special Option	-
Equipment Maintenance	1 checkup year 2	+	1 st checkup year 1	-
Maintenance After 1 st checkup	Yearly		Yearly	

Other: Low flow O2 can currently be used with iVent; Drager Savina manufacturer states that low flow O2 is in the final stages of development for their ventilator.

CONCLUSION

During testing the VersaMed iVent appeared to have the least amount of problems. The fact that the VersaMed iVent requires a VersaMed circuit as opposed to a standard circuit that is interchangeable with other ventilator brands is a major concern. If the VersaMed iVent is chosen we should consider purchasing at least two non-disposable circuits per ventilator in case there is a problem obtaining the disposable circuits.

The Drager Savina did not function well during the decreased compliance test, which could be a large problem in a patient with ARDS. Neither ventilator has an AWR or a fit-to-fly letter and would not be allowed on any aircraft. Internal battery life of both ventilators is short for use as a transport ventilator.

No matter which ventilator is selected, we recommend that exhaled VT is measured daily with a Wright respirometer to insure whenever there is a change in compliance that the set VT is being delivered, because both ventilators displayed values that were different from the values measured by the Wright.

APPENDIX A

Battery Life Test

	Drager Savina	VersaMed iVent201
Test 1 – VT 700, RR12, PEEP5, PS10, PF60,	Vent Stopped / Useable Time 57 Min / 51 Min	Vent Stopped / Useable Time 85 Min / 56 Min
Test 2 – VT 900, RR16, PEEP5, PS10, PF70	47 Min / 43 Min	85 Min / 61 Min

First Battery Life Test

	Drager Savina	VersaMed iVent201
+39 min	“Int Battery Low”	
+51 min	“Int Batt Almost Discharged”	“Low Battery”
+54 min		“Low Battery”
+56 min		“Battery Empty”
+57 min	Ventilator stopped working.	
+62 min		“Need Cal”
+77 min		“VT Not Delivered”
+81 min		Screen fluttered.
+83 min		“Low Min Volume”
+85 min		“Patient Disconnect”
		Ventilator stopped working.

Second Battery Life Test

	Drager Savina	VersaMed iVent201
+34 min		Low Battery”
+39 min	“Int Battery Low	
+43 min	“Int Batt Almost Discharged”	
+47 min	Ventilator stopped working.	
+61 min		“Battery Empty”
+65 min		“Need Cal”
+74 min		“VT Not Delivered”
+80 min		Screen fluttered.
+84 min		“Low Min Volume”
+85 min		Ventilator stopped working.

Battery Charge Time

Ventilator in standby	2 Hours 12 Min	8 hours 27 Min †
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APPENDIX B

Ventilator Evaluation Form

The Army Burn Center is requesting your assistance in the evaluation of two ventilators for use in Army Combat Support. **These ventilators will be used primarily for long-term care for patients who cannot or will not be evacuated to a fixed facility for an extended period of time.** We ask that you give an unbiased evaluation of each ventilator using the following criteria:

VersaMed IVent

Please look through the user manual for no more than 5 minutes and then follow the directions below.

- 1) Was the manual easy to use and to find information?

Comments:

	Very Easy	Somewhat Easy	Neutral	Somewhat Hard	Very Hard	
1)	7	9	2	0	0	AVG=1.7

Start the stop watch, turn the ventilator on and put these settings, SIMV (Volume) VT 700 (70kg patient), RR 12, PS 10, PEEP 5, PF 70, I:E ratio 1:3.

- 2) How easy was it to put the settings in?

Comments:

	Very Easy	Somewhat Easy	Neutral	Somewhat Hard	Very Hard	
2)	13	4	1	0	0	AVG=1.3

- 3) How long did it take you to put the settings in? AVG = 3 Minutes/ 17 Seconds

- 4) Do you prefer the auto settings with the IVent or the way that a standard ventilator starts?

Comments:

	Very Easy	Somewhat Easy	Neutral	Somewhat Hard	Very Hard	
4)	10	3	5	0	0	AVG=1.7

- 5) Start the stop watch and make the following changes to the ventilator, A/C (volume), VT 850, RR 16, PS 5, PEEP 5, PF - 55, I Time - 1.5 seconds

How easy was it to make the changes?

Comments:

	Very Easy	Somewhat Easy	Neutral	Somewhat Hard	Very Hard	
5)	14	3	0	0	1	AVG=1.4

6) How long did it take you to put the settings in? AVG = 1 Minutes/ 17 Seconds

Put the following alarm settings in High RR 30, Low RR 8, High Minute Volume 20L, Low Minute Volume 8L, Apnea 20 seconds, High Pressure 10 above PIP, Low Pressure 5, Leak off.

7) How easy was it to put the alarm settings in?

Comments:

	Very Easy	Somewhat Easy	Neutral	Somewhat Hard	Very Hard	
7)	14	3	0	1	0	AVG=1.3

8) How long did it take you to put the settings in? AVG = 1 Minutes/ 34 Seconds

Drager Savina

Please look through the user manual for no more than 5 minutes and then follow the directions below.

9) Was the manual easy to use and to find information?

Comments:

	Very Easy	Somewhat Easy	Neutral	Somewhat Hard	Very Hard	
9)	1	10	3	3	1	AVG=2.6

Start the stop watch, turn the ventilator on and put these settings, SIMV (Volume) VT 700, RR 12, PS 10, PEEP 5, PF 70, I:E ratio 1:3.

10) How easy was it to put the settings in?

Comments:

	Very Easy	Somewhat Easy	Neutral	Somewhat Hard	Very Hard	
10)	2	6	4	6	0	AVG=2.8

11) How long did it take you to put the settings in? AVG = 6 Minutes/ 31 Seconds

Start the stop watch and make the following changes to the ventilator, A/C (volume), VT 850, RR 16, PS 5, PEEP 5, PF - 55, I Time - 1.5 seconds

12) How easy was it to make the changes?

Comments:

	Very Easy	Somewhat Easy	Neutral	Somewhat Hard	Very Hard	
12)	4	9	3	2	0	AVG=2.87

13) How long did it take you to put the settings in? **AVG = 1 Minutes/ 52 Seconds**

Put the following alarm settings in High RR 30, High Minute Volume 15L, Low Minute Volume 10L, Apnea 20 seconds, High Pressure 10 above PIP.

14) How easy was it to put the alarm settings in?

Comments:

	Very Easy	Somewhat Easy	Neutral	Somewhat Hard	Very Hard	
14)	5	7	4	2	0	AVG=2.2

15) How long did it take you to put the settings in? **AVG = 2 Minutes/ 13 Seconds**

APPENDIX C

Maintenance Data

Drager Savina	
O2 sensors	Replace as needed or every two years
Microfilter	Replace every year
Dust filter set	Replace every year
Blower unit	Replace after 20,000 hrs of operation or eight years†
Lead-gel battery	Replace every 2 years†
	Charge every six months while in storage
Filter in O2 inlet	Replace every 6 years†
Real-Time Clock	Replace every 6 years†
Pressure reducer	Replace every 6 years†
Equipment inspection and service	First inspection at 2 years or after 6,000 hours of operation, whichever comes first. Thereafter annually or after 6,000 hours of operation whichever comes first.†

† - To be performed by Drager Service or factory trained and authorized technical service personnel.

VersaMed iVent201	
Air inlet filter	Replace every 500 hours or one month of operation
	Replace every 5000 hours or annually perform safety check †
Internal battery	Replace every 2 years
	Deep discharge and recharge every 1500 hours or 3 months of use
O2 sensor	Two point calibration every 1500 hours or 3 months of use
	Replace every 5000 hours or annually perform safety check †
Cooling vent inlet filter	Clean every 1500 hours or 3 month of use
	Replace every 5000 hours or annually perform safety check †
Pneumatic assembly battery 5000 hour PM kit	Every 10000 hours or 2 years †
Safety testing and maintenance	Every 10000 hours or 2 years †

† - Authorized VersaMed service personnel must perform the service.